



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

October 7, 2019

Keith A. Matthews, Agent
C/O Oxitec, Ltd
Wiley Rein LLP
1776 K St. NW
Washington, DC 20006

Subject: Data Deficiency
OPP Decision Number: 549240
EPA File Symbol: 93167-EUP-E
Product Name: OX5034 *Aedes aegypti*
Application Receipt Date: April 1, 2019
EPA Company Number: 93167
Company Name: Oxitec, Ltd

Dear Mr. Matthews:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

As previously described in a telephone conversation on September 30, 2019, pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter ending **December 21, 2019** to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes

the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. Vector competence and fecundity of OX5034 mosquitoes compared to wild type mosquitoes are not adequately characterized. Characterize vector competence and fecundity of OX5034 mosquitoes compared to wild type (i.e., not lab strain) mosquitoes.
2. Confirm whether the OX513A strain genetic background is the same as the OX5034 genetic background.
3. In addition, modeling could be performed to determine how the rates of introgression are impacted by EUP parameters (e.g., acreage size, application rate, offspring survival of OX5034, and immigration rate) for Trial A and Trial B designs compared with the parameters in the Jacobina, Brazil release sites.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on November 1, 2019. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** You may work with us to establish a new section 33/PRIA deadline that allows for an appropriate response to the 75 day letter. If you choose this option, you need to contact the Agency not later than **October 18, 2019** to discuss a time frame that allows you to address the deficiencies listed above and the Agency to make a regulatory decision.
2. **Withdraw the application.** Alternatively, you may notify us not later than **October 18, 2019** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review** of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **October 18, 2019**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this

determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application. Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **October 18, 2019** by contacting Eric Bohnenblust by telephone on 703-347-0426 or by e-mail at Bohnenblust.eric@epa.gov or Alan Reynolds by telephone at 703-605-0515 or by email at Reynolds.Alan@epa.gov during the hours of 7:00 am to 4:30 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eric Bohnenblust', with a long horizontal line extending to the right.

Eric W. Bohnenblust
Senior Biologist
Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)